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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,349

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Donald A. Sargent

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06/12/2008

KUSNER & JAFFE

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,349	<b>Applicant(s)</b> SARGENT ET AL.	
	<b>Examiner</b> MONZER R. CHORBAJI	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/08</u> .                                                 | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

**This non-final action is in response to the arguments received on 5/8/07**

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-13 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky (U.S.P.N. 5,552,115) in view of Meloul et al (U.S.P.N. 5,806,551).

Regarding claims 1, 7, and 12, Malchesky teaches the following: a container (figure 4:C) with a generally cup-shaped tray that includes a bottom wall and a continuous side wall, bottom and side walls defining a cavity (figure 4:62, 60, col.6, lines 64-67 and col.7, lines 1-6), a lid attachable to the tray, a fluid inlet in the tray communicating with the cavity (figure 4:72), a fluid outlet in the tray communicating with the cavity (figure 4:70) where each of the inlet and the outlet has a valve assembly (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves moves into an open position for allowing liquid sterilant to enter and exit the tray and when the tray is removed from the decontamination chamber the valves moves into a closing position for sealing the container (col.7, lines 5-6, lines 26-30) and a circulation system (col.6, lines 24-27) such that the cavity is in communication with the circulation system through the valves when the container is placed in the decontamination chamber. Malchesky fails to teach using a flexible valve element being formed as a one-piece and having a movable part and a fixed part in the container that is moved by a mechanical actuator in the decontamination chamber such that the valve element is disposed away from the surface toward the cavity when in open position and the valve element engages the surface when in closed position.

Meloul discloses a flexible valve element (figure 2A:20) being formed as one-piece (col.7, lines 52-55) and having a movable part (figure 1A:70) and a fixed part (figure 1A:58) in the container (figure 1A:18). Meloul teaches that such a structure eliminates the wiper seal that in turn eliminates the pumping and back pressure wave. Meloul further teaches that the flexible valve element is moved by a mechanical actuator (figure 3A:110) such that the valve element is disposed away from the surface (unlabeled inner surface of 14 in figure 1A) toward the cavity (unlabeled inner volume of 18 in figure 3A:20) when in open position (figure 3A:20) and the valve element engages the surface (unlabeled inner surface of 14 in figure 1A) when in closed position (figure 2A:20). In addition, Meloul discloses a flexible valve element having a plurality of radially extending arms (figure 3A:72). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the system in Malchesky with a one-piece movable valve, because it eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave as explained by Meloul (col.9, lines 32-36 and lines 64-66).

Regarding claims 11, 13, 19-20, and 22-23, Malchesky teaches the following: multiple valve assemblies that close and open based on pressure differentials (col.7, lines 25-28); a tray includes multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes a check valve (figure 4:74) that opens and closes independently of other valves; a circulation system (col.6, lines 24-27) with a first fluid inlet line (figure 2:32) and a fluid outlet line (figure 3:36) that communicates with the first fluid inlet port (figure 4:72) and the fluid outlet port (figure 4:70) of a container (figure 4

C) when the container is disposed in the decontamination chamber (col.7, lines 5-6, lines 26-30), fluid inlet (for example, figure 4:72) is in communication with a nozzle (figure 4:78) within the container, fluid inlet is in communication with connectors (figure 4:78) connected with medical instruments (figure 5:78 and 76), a microbial liquid decontamination solution (col.5, lines 53-55) and an essentially closed loop circulation system for circulating the liquid sterilant (col.6, lines 24-27).

Regarding claims 2 and 5, Malchesky fails to teach providing a resilient flexible valve element. Meloul discloses a resilient flexible valve element (figure 2A:20 and col.7, lines 51-52), because such a structure eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave (col.9, lines 32-36 and lines 64-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the system in Malchesky with a one-piece resilient movable valve, because it eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave as explained by Meloul (col.9, lines 32-36 and lines 64-66).

Regarding claims 3-4, 6, 8-10, and 21, Malchesky fails to teach a flexible valve having a first portion that is movable by an external actuator element between an open position and a closed position and that the flexible valve element having a normally closed position. Meloul discloses a flexible valve element (figure 2A:20), because such a structure eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave (col.9, lines 32-36 and lines 64-66). Meloul further teaches that the flexible valve element (20) has a first portion (figure 1A:70) that is movable by an external actuator element (figure 3A:110) between an open position (see figure 3A) and

a closed position (see figure 2A) where the flexible valve element (20) has a normally closed position (2A). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the system in Malchesky with a one-piece movable valve, because it eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave as explained by Meloul (col.9, lines 32-36 and lines 64-66).

Regarding claims 16-18, Malchesky fails to teach flexible elements that are movable by external actuator elements between an open position and a closed position. Meloul discloses a flexible valve element (figure 2A:20), because such a structure eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave (col.9, lines 32-36 and lines 64-66). Meloul further teaches that the flexible valve element (20) has a first portion (figure 1A:70) that is movable by an external actuator element (figure 3A:110) between an open position (see figure 3A) and a closed position (see figure 2A). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the system in Malchesky with a one-piece movable valve, because it eliminates the need for a wiper seal that in turn eliminates the pumping and back pressure wave as explained by Meloul (col.9, lines 32-36 and lines 64-66).

#### ***Allowable Subject Matter***

5. Claim 24 is allowed.

#### ***Response to Arguments***

6. Applicant's arguments see pages 2-3, filed 05/08/2007, with respect to the rejection(s) of claim(s) 1-13 and 16-23 under obviousness of Malchesky in view of Bassett have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Meloul et al as shown above.

Note that Meloul is combined with Malchesky for teaching a flexible valve element (figure 2A:20) being formed as a one-piece (col.7, lines 52-55) and having a movable part (figure 1A:70) and a fixed part (figure 1A:58) in the container (figure 1A:18) where Meloul further teaches that the flexible valve element is moved by a mechanical actuator (figure 3A:110). In addition, Meloul discloses a flexible valve element having a plurality of radially extending arms (figure 3A:72).

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

/M. R. C./